Minutes from the November 13, 2008
Montgomery County Biosciences Task Force Meeting

In attendance

Task Force Members
David Mott, Chair
Bill Bertrand, MedImmune
Ken Carter, Avalon Pharmaceuticals
Christine Copple, Starise Ventures
Claire Driscoll, HGRI
Stewart Edelstein, Universities at Shady Grove
Dennis Fallen, Fisher BioServices
Paul Fischer, GenVec
Jennie Hunter Cevera, UMBI
Kazem Kazempour, Amarex Clinical Research
Steven Mayer, CoGenesys
Devinder Poonian, DP Clinical
Michael Richman, Ammplimmune
Bill Robertson, Adventist Healthcare
Ted Roumel, UMBI
Ed Rudnic, Former CEO, Middle Brook Pharmaceuticals
Rahul Singhvi, Novavax
Rick Zakour, MD Bio/MD Bio Foundation

Other Attendees
Elaine Amir, Johns Hopkins University
Mojdeh Bahar, NIH
Keith Baker, Johns Hopkins University
Robert McGlotten, DBED
David McDonough, Johns Hopkins University
Cherie Nichols, Johns Hopkins University
Ruchika Nijhara, Georgetown University
Elliot Olstein, Carella, Byrne et al
Mike Rollor, UMD Baltimore
Mark Rohrbaugh, NIH
Claudia Stewart, Georgetown University
Ben Wu, DBED
Ralph Blakeney, SBDC

Montgomery County
Peter Bang, Department of Economic Development
Tina Benjamin, Department of Economic Development
Joyce Fuhrman, Office of Council President Knapp
Pradeep Ganguly, Department of Economic Development
Mike Knapp, Council President
John Korpela, Department of Economic Development
Janis Peters, Department of Economic Development
Corinne Rothblum, Department of Economic Development
Diane Schwartz-Jones, Office of the County Executive
Tom Street, Office of the County Executive

John Korpela, manager of Montgomery County's Business Innovation Network (BIN), welcomed the task force to the Germantown Innovation Center - the fifth, and newest, of the County's business incubators. He gave a brief overview of the BIN program, and offered to take interested attendees on a tour of the facility after the meeting.

Task force chair Mott noted that at the group's first meeting in October, there had been discussion about the increasing difficulty of getting technology out of local universities and NIH, and he therefore suggested that this second meeting focus on tech transfer. The third meeting will focus on entrepreneurialism –what elements are missing in Montgomery County that have made other regions like the San Francisco Bay Area a hub of creativity, entrepreneurial buzz and innovation? Steve Mayer has offered to identify people who can talk about what works well elsewhere. Other future topics will include marketing and creating good management teams.

The minutes from the October 6th, 2008 meeting were approved.

Minutes from the November 13, 2008
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Guest Presentations

National Institutes of Health Office of Tech Transfer

Mark Rohrbaugh, director of the NIH Office of Tech Transfer (OTT), gave an overview of OTT, which manages the patenting and licensing of inventions coming out of FDA and NIH's intramural research. At the institute level, OTT negotiates CRADAs and MTAs. There are over 18,000 people at NIH, including 6,000 MD/PhD scientists and thousands of post-docs. Not all post-docs stay in the area – Montgomery County needs to consider opportunities to keep them here.

NIH has lots of IP – over 3,500 patents and thousands of unique biological materials. It hosts the largest clinical research hospital in the world on its campus in Bethesda. There are opportunities to triangulate the expertise of the NIH, local universities and the private sector, and there are examples of people moving from NIH to private companies. In some cases they move from tech transfer functions to working for venture capital (VC) firms.

NIH runs a tech transfer certification program targeted at scientists –mostly post-docs – that provides six semester-long courses in business development, tech transfer, etc.: http://www.faes.org/graduate_school. Few industry people participate – David Mott suggested that MedImmune's junior business development staff consider enrolling. The fee is modest at $250/course, and the program is also a great way to network.

Collaborations with NIH are possible through material licenses, clinical trial agreements, and CRADAs, which are the only legal option to license NIH inventions and receive funds. There are about 1,400 commercial licenses from NIH in the U.S. About 80 of these are in Maryland. NIH has over 200 licensed products. Marketing initiatives include the 'Pipeline to Partnerships' to push mid-stage technologies forward towards licensing, mergers and acquisitions (www.ott.nih.gov/p2p). Examples of products developed through NIH CRADAs include FluMist (MedImmune), Taxol (Bristol-Meyers Squibb) and Havrix (GlaxoSmithKline).

New conflict of interest (COI) rules introduced in 2005 changed the way that NIH scientists can collaborate with the private sector. The new laws prohibit any outside consulting with biotech and pharma companies. As part of their official duties, NIH scientists can engage in scientific collaborations, but receive no personal compensation. Rohrbaugh acknowledged that the COI rules have perhaps had a chilling affect on how scientists in NIH and industry can work together, and NIH hopes to continue to clarify what is possible.

A task force member noted that it is not possible for NIH to take equity or to offer fee-for-service arrangements through which private companies can access excess equipment at NIH. This has tied NIH's hands a bit, and smaller companies that need capital are sometimes deterred from trying to access NIH technologies. Another participant commented on how different NIH's COI rules are from universities, which greatly hampers collaboration. It's not simply a communications issue.

Rohrbaugh noted that in principle, as part of their official duties NIH scientists can collaborate. However, as a task force member pointed out they have no financial incentive to do so. Task Force Chair Mott commented that he and other current and former biotech CEOs had dinner recently with Dr. Zerhouni, former director of NIH. The biotech CEOs expressed their view that private collaboration with NIH has slowed considerably in recent years. Dr. Zerhouni said he did not think this was the case, and that NIH has in fact been issuing more licenses. A task force member asked what the quality of these licenses is. Mott observed that in earlier days, most major programs at MedImmune had a senior NIH scientist collaborator, and they looked to NIH scientists to help them take technology and commercialize it. This

does not happen anymore, and NEA, the VC firm he now works for, is not forming any companies with NIH IP. Rorbaugh responded that they need to find ways to incentivize NIH scientists to collaborate and not view it as a risk to their own core research. A task force member said they are seeing a change in tech transfer – now it is more in line with a longer-term view. Another commented that her institution is not doing as many kick-them-out-quickly licenses. Within the University of Maryland system, 10 years ago all of the campuses together and agreed to let individual campuses manage conflict.

Rohrbaugh explained the genesis of the NIH COI rules. A couple of NIH scientists violated the previous industry collaboration rules and then lied about it, engendering the ire of Congress. As a result, a decision was made that to preserve NIH's scientific independence and reputation, the rules needed to be changed. A participant suggested that the task force talk about the COI issue with the Obama transition team. It was also suggested that the task force take these concerns to Governor O'Malley and Congress, and work with them to modify the COI rules. Task Force Chair Mott suggested the establishment of a small subcommittee that will seek to summarize views on tech transfer challenges at NIH due to the existing COI laws and then meet with Chris Van Hollen and other members of Maryland's congressional delegation. Corinne Rothblum will solicit volunteers for this subcommittee and schedule its initial meeting.

Federal Laboratory Consortium for Technology Transfer (FLC)

Mojdeh Bahar, Chief of the Cancer Branch in NIH's Office of Technology Transfer, presented on FLC. She coordinates mid-Atlantic FLC, the region richest in federal labs. She noted that during a pre-meeting conference call, Task Force Chair Mott brought up an anecdote to illustrate that people don't want to do business with NIH. NIH doesn't see it this way, since the number of licenses has increased. NIH recognizes that the outside perception is different, however, and wants to hear ideas, suggestions and comments about how to change this perception. One thing Bahar thinks people miss are the informal relationships that were formed when NIH was an open campus, before security became very tight.

The FLC is composed of tech transfer professionals from 700 labs and 18 departments and agencies, which collectively include 100,000 scientists and engineers. Initiatives in the mid-Atlantic region include:

1) Education about federal labs for the business community to demystify them;
2) Increased outreach and visibility;
3) Establishment of sub-regions;
4) Sector-based regional network initiatives, such as for biotech in Montgomery County;
5) Fostering technology-based economic development initiatives; and
6) Cross-pollination, co-sponsorship with other professional associations and regional economic development initiatives.

Bahar said she thinks that people especially want more of the latter. An example of this is the upcoming (February 2009) Bioinformatics Conference. Another is Fed Tech Net (FTN), which was initiated by the Montgomery County Department of Economic Development. FTN is a forum for federal tech transfer professionals to get together (at different federal labs) and talk about how best to serve the business community and foster technology-based economic development.

FLC holds an annual Mid-Atlantic Region Annual Conference. Very few industry partners come to these annual events, which bring together all of the movers and shakers from federal labs and a host of economic development professionals. They would like to see more private industry attend in order to foster more public-private collaboration. They also conduct other outreach activities to enhance the visibility of FLC. This includes the use of federal facilities for meetings, co-sponsorships and presentations, and social networking opportunities to enhance interaction. FLC also provides an

educational series that explores different facets of government tech transfer, including workshops to better understand industry perceptions, and are considering Pod casts or web casts to help explain the rationale for the NIH COI provisions, and to help foster better federal-industry working relationships.

A participant asked how we to inventory all of the federal assets that are there to make it easier to link them with industry. While they have no problem reaching budding entrepreneurs, he finds it difficult to reach mid-level companies. Someone noted that they are working on this with TEDCO. Pradeep Ganguly, director of the Montgomery County Department of Economic Development (DED) said that DED is trying to be the conduit to help companies take advantage of information through a new initiative started about three months ago. Someone asked if County biotech businesses are aware of this initiative; Ganguly said it is very new and they may not be yet.

University of Maryland Biotechnology Institute (UMBI)

Ted Roumel, vice president for research, innovation and commercialization gave an overview of UMBI and its tech transfer program. Prior to joining UMBI he spent 11 years in tech transfer at NIH and two years as a senior advisor to the president of PHARMA.

For most universities, tech transfer requirements came into being in the 1980s with the passage of laws that required university recipients of federal funding to seek to commercialize the results of their research. Today, tech transfer is the 'third leg' of universities, which are viewed as a key engine for job creation and economic development. He noted that in the United Kingdom, it is formally a third leg in the mission of all public universities.

UMBI is not a degree granting institution; rather, it is totally devoted to research and development. It has four existing centers around the state of Maryland as well as one virtual center and one in development on the eastern shore, which will focus on agriculture and biotech. UMBI's mission is focused on:

- Conducting cutting edge research in biotechnology and making fundamental discoveries;
- Generating innovative solutions to practical problems;
- Developing new technologies for commercialization;
- Mentoring the next generation of the biotech workforce*; and
- Promoting economic development.

*UMBI has a loaner lab program through which they provide a curriculum and materials to schools. The program is totally voluntary, not state funded. They also partner with MDBio to support a mobile biotech lab which serves as a classroom on wheels.

At its Shady Grove campus, UMBI has a GMP facility for bio manufacturing phase I and II. They can also conduct complex genomic sequencing there and have insect transformation facilities and plant transformation facilities, which they see as the next generation of research. The Shady Grove and Baltimore locations both have incubator space.

UMBI is on the leading edges in research and deals with a wide range of technologies that require them to have highly qualified people knowledgeable in all areas. The institute's resources include exceptional professional staff and training programs. Traditional activities include identifying new technology, protecting their IP, marketing and licensing technologies and spinning off companies. They have 'embedded' some of their tech transfer staff with scientists so that the research work is not seen as a black box. This is similar to what NIH is doing to have its tech transfer coordinators work with scientists. UMBI works with the ACTIVATE program, MIPS and TEDCO. In addition, the MD Drug Discovery and Development Network is a new concept that looks at the entire drug discovery process and plugs in

the resources available through state and private institutions. They are working with DBED on this to make more people aware of it and of the resources available to companies.

The Invenio Network (http://www.invenioip.org/) is an attempt to put in a single portal all of the technologies that are available for licensing in the state of Maryland. It is intended as a clearinghouse for available technologies, not a brokerage. Mike Rollor at the University of Maryland is the key contact.

UMBI institute is very business oriented and flexible in its terms, and offers fee-for-service arrangements. It views industry as a partner; commercialization is seen as a long-term commitment and the institute seeks to collaborate with industry partners that are looking for long-term relationships. Roumel thinks that companies are holding back with licensing; they want to feel out what kind of a collaborative partnership they can form before they license technology. Proof-of-concept requirements are a constant issue; many companies want to see that a technology works before they will make a commitment to license it.

Roumel noted that they need additional resources to meet their commercialization needs. Additional professional personnel are needed to identify discoveries, market them, develop partnerships and licensing agreements and monitor outcomes. More professional staff are also needed to help spin out new companies and assist with IP costs to meet UMBI's target of spinning out 300 companies over the next 10 years. Roumel noted that the USM numbers are far lower than other university systems. Proof-of-concept funding and translational research centers are also needed to bolster stagnating technologies and get them to the next stage. There is a funding gap between great ideas and where VCs and others are interested in investing.

He believes there needs to be a change in attitudes, and a reward system that encourages university faculty to think more about the commercialization of their research findings. All academic institutions need to work on this, and it has been discussed at the Maryland Life Sciences Advisory Board (LSAB) meetings. The LSAB recommendations will address possible barriers in state regulations and policies.

It takes a lot of effort to market the institution and available technologies, and there are not enough resources devoted to marketing. The state education system has lots of requirements, and tech transfer is not its highest priority. At UMBI they try to make everyone a marketer, and to ensure that all staff understands what technologies are available for licensing, as well as what they are and what they can do.

Johns Hopkins University (JHU) Office of Technology Transfer
Keith Baker, Senior Director for Licensing, gave an overview of JHU's tech transfer mission to commercialize university innovations for the public good by:

- Encouraging and supporting invention disclosure;
- Encouraging and supporting entrepreneurs;
- Effecting technology development and licensing;
- Increasing available university funding; and
- Protecting and managing the university's IP

The tech transfer office includes all of JHU's schools except the Applied Physics Lab. The licensing division has four teams with about three professionals each; three of the teams are oriented towards the life sciences. On average, they generate about three – five start up companies are year; in FY08 12 companies were created; six are corporate/VC backed and seven are based in Maryland. Since 2000, JHU's Office of Tech Transfer has spun out 42 start-ups.

The challenge of transitioning from the lab to market (the "valley of death") is critical.
JHU is thinking more about how to traverse this divide by:

- Opening its doors for consulting. Faculty can consult up to 20 percent of the time with approval
- Allowing companies to access the specialized equipment on its campuses
- Conducting industry-sponsored research. In FY08, they had $400 million in industry sponsored research; a big chunk for clinical trials. Faculty are ready to talk about alternate sources of funding
- Other industry connections: more and more departments and faculty are becoming open to outside suggestions for research areas
- Investor conferences open to all who are interested. In 2007 the focus was on oncology investors; this year on neuroscience; in 2009 the focus will be on cardiology
- Alliance for Science and Technology: brings in thought leaders from VCs, pharma and biotech so that JHU faculty can pitch their research and get real feedback
- A new life sciences park – going up adjacent to the medical school in Baltimore

Task Force Chair Mott said that he would like to get a two-pager on JHU's spin-off companies/recent formations. Baker said he would provide this.

Elliot Olstein, Intellectual Property/Technology Transfer Attorney
Chairman Mott introduced Elliot Olstein as the most experienced intellectual tech transfer lawyer he knows.

Olstein spoke about some general trends he has been seeing recently:

- Mid-sized companies are not doing business with universities; they find it difficult to work with academic researchers, who are not responsive to their needs
- University tech transfer offices around the country are becoming more important as profit centers, which makes negotiations more difficult. Tech transfer is a big business - there is lots of pressure on tech transfer offices to get higher licensing revenues, especially when they are compared to places like Stanford, and to maximize returns. A lot of people come away from the process feeling burned
- It is getting harder and harder for smaller start-ups to get financing. In the "old days" VCs would look for technology to fund; today they are not doing this as much. Now the trend is for entrepreneurs to find technologies, do the deals and then get VCs to back them. The challenge is how to get VCs more interested at an early stage – they find it easier to deal with start-ups after they have been around for a while

Tech transfer offices need to work on creating more of a perception that they are industry-friendly. Start-ups generally can't afford licenses as they don't have money up-front. If tech transfer offices really want to encourage commercialization, they should work to be more flexible in understanding a new company's needs. Deals should be structured to make more exceptions at the front end and to look more to back-end revenues.

Olstein's impression is that Montgomery County is doing a lot to get new business through its incubators, tax incentives, etc. He suggested that the County also 'package' deals for potential entrepreneurs. There is no lack of entrepreneurs in the area; lots of companies have number twos and threes who would love to be entrepreneurs but don't have the time to pursue it. He proposed that the County look for technologies to match up with talented people, access to lab facilities and financial incentives and, facilitate contacts with VCs. This kind of packaging would provide potential entrepreneurs with an inventory of resources and a one-stop place to go.

While providing business counseling to start-ups is good, Olstein believes that it would be far better to put together a technology package so that people have an inventory of options to draw on. Olstein suggested that DED identify promising technology with licensing opportunities and get options on these technologies, which would help attract people to the area to start up new companies.

A task force member said that most universities are more flexible now than they were in the past. They now have deals where they are not taking anything up front but are all back-end loaded. He noted that universities have limited resources; they use revolving funds from licensing fees to finance new technologies. He also observed that the metrics currently being used are not measuring the right thing - what does the number of spin-offs or patents issued really mean? He believes that what should be tracked are *outcomes* - what technologies are being moved out and creating products that are helping people.

Ganguly said the DED would look at Olstein's suggestion about creating a bank of technologies and packaging incentives to help entrepreneurs. Task Force Chair Mott asked if there is a way to bring together disparate resources including web-based information, available incubator space, etc. He suggested that Ganguly come back at a future meeting to talk about what DED can do to help move resources to move technologies further along.

A participant suggested that DED also assess some of the structural defects in the marketplace and look at how to set up structures that will allow it to function more efficiently, such as a strong social networking infrastructure, better databases, etc. Task Force Chair Mott said there should also be more national meetings like the ones JHU is sponsoring – they are great and help the local biomedical community.

Task Force Chair Mott asked if task force members had any final comments. One said that the response time from tech transfer offices is an issue - he is dealing with this right now in another part of the country. He suggested that tech transfer offices look at their response times as this can chew up a lot of time for companies. Another task force member said that it works both ways – tech transfer offices sometimes have difficulty reaching company presidents until IPOs are imminent. Task Force Chair Mott noted that some of these issues can be systemic - there are not good processes in place.

The next task force session will focus on entrepreneurship. What Montgomery County does well, what is missing for company start-ups and how to build good management teams. The meeting adjourned at approximately 10:30 a.m.